# UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND; PIRELLI ARMSTRONG RETIREE MEDICAL BENEFITS TRUST; TEAMSTERS HEALTH & WELFARE FUND OF PHILADELPHIA AND VICINITY; PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND; DISTRICT COUNCIL 37, AFSCME -HEALTH & SECURITY PLAN; JUNE SWAN; MAUREEN COWIE and BERNARD GORTER,

Plaintiffs,

v.

FIRST DATABANK, INC., a Missouri corporation, and McKESSON CORPORATION, a Delaware corporation,

Defendants.

Civil Action: 1:05-CV-11148-PBS

Judge Patti B. Saris

### MCKESSON CORPORATION'S SURREPLY IN OPPOSITION TO CLASS CERTIFICATION

[REDACTED VERSION]

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OTHER
Average Wholesale Price"AWP"
Express Scripts, Inc"ESI"
First DataBank"FDB"
Pharmaceutical Benefits Manager"PBM"
Third Party Payors"TPP"
Wholesale Acquisition Cost "WAC"

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#### INTRODUCTION

In its Opposition to plaintiffs' class motion, McKesson demonstrated that plaintiffs' claim of inflated AWPs and spreads raised predominantly individual issues of third party payor ("TPP") knowledge and response. Plaintiffs' efforts to denigrate evidence of such knowledge and response serve only to make perfectly clear: that what TPPs knew, when they knew it, and how they responded to alleged artificial AWP increases inevitably lead to a host of individual TPP-by-TPP fact issues for trial. These very same individual issues likewise render Dr. Hartman's formulaic methodology for computing class-wide impact and aggregate damages, in a word, useless. On this ground alone, certification should be denied.

While it is therefore unnecessary for the Court to enter the economist battlefield, it now also becomes clear that the extreme "zero knowledge — zero mitigation" thesis which is the lynchpin for Dr. Hartman's opinions is not only contradicted by the facts, but is also flawed as a matter of simple economic theory, and, moreover, undermined by Dr. Hartman's own admissions and those of plaintiffs' co-expert witness, Susan Hayes.

Finally, while there are some factual differences between this case and the AWP-MDL case against drug manufacturers, the two grounds upon which the Court denied certification for self-administered drugs there — predominance of individual issues and lack of manageability — are equally applicable here, and compel denial of plaintiffs' class certification metion. See In Re Pharmaceutical Industry Average Wholesale Price Litigation, 230 F.R.D. 61 (D. Mass. 2005) ("Pharm. III") (denying certification of TPP and consumer classes alleging AWP inflation in self-administered drugs).

I. PLAINTIFFS FAIL TO REFUTE THAT TPP KNOWLEDGE OF THE WAC-AWP SPREAD INCREASE CREATES PREDOMINANTLY INDIVIDUAL ISSUES.

In their opening brief, plaintiffs insisted that "there is no evidence" that any TPP, over a 3-1/2 year period, was ever aware of the 5% increase in the WAC-AWP price spread as reported by First DataBank ("FDB") from 2001-2005 (the "Spread Increase"). (Pl. July 17 Br. at 14; Pl.

Am. Br. at 2, 6, 12.) Even after McKesson provided in its Opposition evidence directly contrary, plaintiffs still continue to argue in their Reply Brief that no TPP "was ever aware" of the 5% Spread Increase. (Pl. Reply Br. at 1.) Why are plaintiffs so adamant in denying TPP knowledge when the evidence conclusively establishes the opposite?

It is because Dr. Hartman has already conceded that if TPPs were aware that AWPs had been artificially inflated, they would immediately and aggressively seek to negate the impact of the increased AWPs by obtaining price concessions from PBMs and retailers. (Schechter Sur. Decl. Ex. 25, Hartman Dep. 82:14-85:3.) Indeed, this concept is the centerpiece of Dr. Hartman's declaration in support of the FDB settlement in this case.<sup>2</sup> (See Hartman Sett. Decl.; see also Willig Rebuttal Decl. ¶ 69.)

Consistently, the new reply declarations of the named plaintiffs filed with plaintiffs' Reply Brief state that if they had been aware of the Spread Increase, they would promptly have negotiated recovery of *all* of their increased costs attributable to increased AWPs.<sup>3</sup> For example, named plaintiff Pirelli Armstrong states: "Had the Trust known about the Scheme or about the increase in mark-ups, we would have acted to eliminate the entire increase." (Pl. Reply Br. App. B ¶ 7.) Each of the other named plaintiffs gives substantially similar testimony in their

Often, plaintiffs (as well as Dr. Hartman) appear purposely to confuse knowledge of the so-called "scheme" with knowledge of the 5% change in the WAC-AWP spread. Clearly, Dr. Hartman's position turns on whether TPPs were aware of the spread change, not knowledge of an alleged conspiracy. Accordingly, we will be referring to knowledge of the 5% Spread Increase and increased AWPs.

<sup>&</sup>lt;sup>2</sup> Specifically, Dr. Hartman states that with knowledge of the change from a 25% to a 20% markup, it is likely that not all reduced costs will be passed on to TPPs because "it is possible that retailers would attempt to renegotiate the percentage discount off FDB's AWP to defeat the reduction in the allowed amount to be reimbursed." (Hartman Sett. Decl. ¶ 9, n.14.) Strategies to carry out such renegotiations "will be developed individually ε.nd over time, as different market participants assess their strategic alternatives, observe the strategies of other market participants and ultimately implement their consequential strategies." (*Id.* ¶12, n.19.)

<sup>&</sup>lt;sup>3</sup> Contrary to these new declarations, Dr. Hartman argues that TPPs could not have "instantaneously" mitigated the impact of increased AWPs due to the Spread Increase. (Hartman Rebuttal Decl. ¶3; Attach. C, ¶ 18.) Plaintiffs argue the same. (Pl. Reply Br. at 1.) Since Dr. Hartman denies there was *any* mitigation, instantaneously or otherwise over 3-1/2 years, his argument hardly supports his zero mitigation thesis. Second, Dr. Hartman's argument ignores how TPPs could and did recoup increased costs due to the Spread Increase. (See Willig Jan. Rep. ¶¶ 29-30, App. A.) Even the new declarants agree that TPPs who knew of the Spread Increase would recoup all of their increased costs.

declarations. 4 (Pl. Reply Br. App. B (excerpting declarations of named TPP plaintiffs and other TPPs).)

In sum, it has been virtually conceded that if TPPs were aware of the Spread Increase, individual fact issues (what did they know, when did they know it, and what did they do in response) would defeat certification under Rule 23(b)(3). Little wonder, therefore, that in their Reply, plaintiffs and Dr. Hartman are pressed to advocate the indefensible position that not even one TPP (out of 11,000-plus TPPs), at any time over 3-1/2 years, ever became aware of the Spread Increase, or the "change in formula," as plaintiffs describe it. (Pl. Reply 3r. App. A.) In support of their position, plaintiffs: (1) attempt to dispute all of the powerful evidence to the contrary; (2) rely on a brand new regression analysis created by Dr. Hartman; and (3) then ask the Court, in effect, to decide on the merits that plaintiffs "zero knowledge — zero mitigation" position has been proven. In each of these respects, plaintiffs are simply wrong.

### A. Ample Evidence Demonstrates That TPPs Were Aware of the Spread Increase.

In opposition to plaintiffs' class motion and proffer of evidence, McKesson filed a detailed counter-proffer that contained 17 paragraphs of evidence with supporting citations and exhibits demonstrating conclusively that, from a number of sources (including timely PBM notification), TPPs were advised of the Spread Increase and increased AWPs. (Proffer ¶ 8-24.) These 17 paragraphs from McKesson's Proffer, along with newly acquired evidence of TPP knowledge discussed below, are collated together and set forth in "Appendix A," attached hereto.

<sup>&</sup>lt;sup>4</sup> The same is true for absent members of the putative TPP class. For example, the Declaration of Shawn Barger, Director of Clinical Pharmacy Management for Av-Med Health Plans, states: "If we had learned that the increases in AWP from 120% to 125% of WAC were arbitrary and unrelated to manufacturers' or wholesalers' price increases, I believe my company would have taken steps as promptly as practicable to mitigate the increased amounts we would have had to pay the pharmacies accordingly." (PI. Reply Br. App. B ¶ 1.)

<sup>&</sup>lt;sup>5</sup> Plaintiffs make a meager effort to argue that variations in knowledge are insufficient to bar certification where other issues unite the class, citing *In re Tyco Int'l Ltd. Multidistrict Litig.*, 236 F.R.D. 62 (D.N.H. 2006), and *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 296 (1st Cir. 2000). (Pl. Reply Br. at 20.) Yet neither case deals with the issue of knowledge and both stand only for the general rule that Rule 23(b)(3) is satisfied where common issues predominate over individual ones. As McKesson has shown, that is not the case here.

By way of example, in January 2002, Express Scripts ("ESI"), one of the three largest PBMs in the country, learned of the Spread Increase and promptly conducted an in-depth analysis of the AWP changes — including a discussion with Kay Morgan of FDB who candidly advised ESI that virtually all 20% WAC-AWP spreads were moving to 25%. (See App. A ¶¶ 1-5.) Just as predicted by the Court's appointed expert, Dr. Berndt, ESI promptly advised its TPP clients of the Spread Increase, recommending that TPPs "put cost management strategies in place." 6 (Id. ¶¶ 7-8.)

Nor was notification from PBMs the only way TPPs were put on notice of the Spread Increase. As set forth in Appendix A, TPPs learned of the increase on their own (e.g., , which first noticed increases in AWP-based rebates), from drug manufacturers which also learned of the AWP increase "from more than one pharma (e.g., company"), from auditors (e.g., Peabody Energy Corporation, which learned from KPMG that First Databank's AWPs had become higher than those of Redbook), and from third-party claims administrators (e.g., Humana, which learned from Argus Health Systems that First Databank's AWPs were now higher than those of Redbook ). (App. A ¶¶ 11-13.)

Newly obtained evidence, discovered since McKesson deposed absent TPP class members, reveals that even TPPs whom plaintiffs claim had no knowledge of the Spread Increase were so advised. Thus, Harvard Pilgrim, a member of the purported TPP class, testified at a Rule 30(b)(6) deposition that it had no knowledge "of whether there has been any increase in the spread between WAC and AWP in the period since [2000] . . ." (Grande Dep. 47:8-13, cited in Pl. Reply Br. App. A ¶ 3.) Yet a May 9, 2002 document, produced to plaintiffs in the MDL by a drug manufacturer, reveals that a Harvard Pilgrim representative actually mentioned the 5% Spread Increase to representatives of a drug manufacturer before that date. The document goes on to state that Harvard Pilgrim is:

<sup>&</sup>lt;sup>6</sup> As discussed in Part II below, Dr. Berndt advised the Court in the AWP MDL that because of intense competition among PBMs, "even if the self-administered AWPIDs were artificially inflated, injury and damages to third party payors do not follow, particularly on a class-wide basis." This is because PBMs would use their bargaining power to recapture additional margins from pharmacies and pass them on to their clients, the TPPs. (Berndt Rep. ¶ 206.)

in the process of renegotiating their retail contracts because of this, potentially to a WAC  $\pm$ % agreement in lieu of AWP  $\pm$ %.

(Schechter Sur. Decl. Ex. 28, MDL-

Similarly, Tina Wong, the Rule 30(b)(6) designee of Blue Cross and Blue Shield of Montana, testified that her only understanding of the relationship between WAC and AWP came from a conversation she had in 1997 with a pharmacy consultant. (Schechter Sur. Decl. Ex. 24, Wong Dep. 101:10-102:4). Yet documents produced to the parties by ESI after Ms. Wong's deposition reveal that Ms. Wong personally received ESI's advisory that FDB's WAC to AWP relationship had increased from 20% to 25%. (Schechter Sur. Decl. Ex. 25C, ESI-414-3677-78.)<sup>7</sup> Perhaps that's why BCBS Montana made changes to member copay levels in response to increases in drug prices, as Ms. Wong testified. (Schechter Decl. Ex. 3A, Wong Dep. 72:3-73:18.)

Likewise Humana, another of the four absent TPP class members deposed by McKesson, candidly testified at its deposition that it was informed by a claims administrator of the Spread Increase. (Schechter Decl. Ex. 12A, Fleming Dep. 160:11-15.) Indeed, it now appears that 75% (three out of the four) of the absent TPP class members McKesson deposed had knowledge about the Spread Increase during the Class Period. Which individuals at each TPP had what knowledge, when it was obtained, and how each TPP responded are decidedly individual issues that cannot be explored at a class trial. The newly discovered evidence not only confirms that TPPs knew of the Spread Increase, but also shows why at trial McKesson is entitled to cross-examine each TPP to determine these facts, and to test the credibility of each of these witnesses.

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<sup>&</sup>lt;sup>7</sup> Plaintiffs omit this fact when they cite Ms. Wong's testimony in their Appendix A to their Reply Brief, entitled "TPP Testimony Regarding Lack of Knowledge of the Scheme or Any Change in Formula."

## B. Plaintiffs' Unfounded Denigration of Evidence of TPP Knowledge Only Serves to Underscore the Predominance of Individual Issues.

In their assault on McKesson's evidence of TPP knowledge, plaintiffs mainly leave the "heavy lifting" to Dr. Hartman, presumably on the erroneous presumption that a Ph.D's refutation of this evidence may appear more credible. It does not. 8

To start with, Dr. Hartman's efforts to now prove "zero knowledge — zero mitigation" by TPPs is somewhat surprising since at his earlier deposition in this case he testified that he did not know whether or not TPPs knew of the Spread Increase; that he had been asked to assume that TPPs could not respond to the increase; and most importantly, that it made no difference to his opinion whether or not TPPs knew. (Schechter Sur. Decl. Ex. 25, Hartman Dep. 62:10-70:12, 143:19-144:13.) Thus, Dr. Hartman testified:

Well, factually, whether third-party payors knew or whether they all knew, whether some of them knew, whether none of them knew is hypothetical to what I've — to the opinion I'm rendering here.

(*Id.* Hartman Dep. 66:9-12.)

In contradiction of what he now espouses, Dr. Hartman went on to concede that:

I — I assume that many third-party payors were unaware of the third — of the change based on what I've seen of awareness of third-party payors, period. . . . Many is — you know, could be 50/50.

(*Id.* 69:9-14; 70:10-21.) He explained, however, that "what [he was] asked to assume is that . . . there was this scheme, the third-party payors were not able to respond to this scheme." (*Id.* 143:19-144:13.)

Second, and more important, the dozen or so "findings of fact" regarding TPP knowledge made by Dr. Hartman are based on nothing more than his so-called "review of the record" (e.g.,

<sup>&</sup>lt;sup>8</sup> Plaintiffs devote considerable time demonstrating that some TPPs were impacted by higher AWPs. (Pl. Reply Br. at 2-10.) McKesson does not contend that no TPP was impacted by the Spread Increase, nor does Dr. Willig. (Willig Rebuttal Decl. ¶ 29.) Rather it is the plaintiffs and Dr. Hartman who contend *all* were, and that none could or did mitigate or negate that impact over a 3-1/2 year period. The truth is that many TPPs *did* know about and respond to the Spread Increase, giving rise to predominantly individual issues of fact, even under plaintiffs' theories of causation.

"there is nothing in the record to suggest" or "I find no evidence in deposition testimony I have reviewed") and accordingly are deserving of no weight whatsoever.

Perhaps most partisan of all are Dr. Hartman's "fact findings" regarding ESI's April 2002 notification of the Spread Increase to its client TPPs. The letter was sent under the heading, "Urgent! Emerging Therapeutics Issues Communication." Here is what ESI's letter to the TPPs told them:

#### Average Wholesale Price Increase

Pharmaceutical manufactures make price changes throughout the year. As we have documented in Express Scripts' annual Drug Trend Report, for the last four years the average increase in Average Wholesale Price ("AWP") has exceeded 5%. The first wave of price increases typically take place in the January through February timeframe. Over the last couple of years these increases have averaged 1 to 1.5%. This year, however, the increase for this period January through February timeframe is closer to 2.5%. The increase for this period also includes an adjustment to increase the difference between wholesale acquisition cost (WAC) and AWP for certain drugs. In other words a little less than half of the total increase is due to AWP increases that are in excess of the corresponding increase in WAC.

Upon our inquiry to our pricing service, First Data Bank (the industry's primary source for AWP information), the recent AWP adjustments were made to establish a more consistent relationship with WAC. As this trend indicates, it is more important now than ever to put cost management strategies in place.

(App. A  $\P$  7; emphasis added.)

In an effort to undermine the obvious import of ESI's letter, Dr. Hartman first "opines" that "I have seen no evidence that the letter was widely distributed," which may be taken to mean "I really don't know." Next, Dr. Hartman cuts to the heart of his attack, throwing even-handed "analysis" to the wind:

The letter is fairly non-specific and uninformative to TPPs citing primarily increasing trends in AWP . . . .

<sup>&</sup>lt;sup>9</sup> Dr. Hartman, like plaintiffs' counsel, points to the testimony of the named plaintiffs, who for the most part say they were unaware of the "Scheme" as opposed to the 5% Spread Increase. (Hartman Rebuttal Decl. Attach. D, Pl. Reply Br. App. B.) Reliance on this testimony, including the self-serving declarations of the named plaintiffs, underscores the intense factual nature of these issues. At trial the credibility of each of the self-serving assertions (as well as any from the other 11,000 TPPs) will be tested before a jury.

(Hartman Rebuttal Decl. ¶ 17.)

Hardly so. ESI plainly is reporting to TPPs the increase in AWPs published by FDB in January and February of 2002, nearly half of which ESI identifies as due to the increase in WAC-AWP spreads, and not to increased drug costs (WAC). Moreover, ESI goes on to inform the TPPs that ESI has spoken directly with FDB, the publisher of these AWPs, who advised ESI that the recent WAC-AWP increases will be applied to more drugs in the future in order to establish a "more consistent relationship" between WAC and AWP. The letter ends with ESI's recommendation that TPPs take immediate action in response to the Spread Increase.

All of Dr. Hartman's so-called "fact findings," which are collected and set forth in Appendix B, hereto, are gratuitous and unsupported, and in any event entitled to no more weight than the corresponding unsupported contentions in plaintiffs' Reply Brief. Courts routinely reject such efforts to cloak what is nothing more than a lawyer's argument under the guise of purported expert testimony. See 4 J. Weinstein & M. Berger, Weinstein's Federal Evidence § 702.03[3] (2006); In re Air Crash Disaster at New Orleans, 795 F.2d 1230, 12:33 (5th Cir. 1986) ("trial courts must be wary lest the expert become nothing more than an advocate of policy before the jury. Stated more directly, the trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument."); Green v. Kinney Shoe Corp., 715 F. Supp. 1122, 1123 (D.D.C. 1989) ("expert testimony should not be admissible when the proposed testimony infringes on one of the decisions that is entrusted solely to the jury . . . ").

Indeed, Dr. Hartman's "fact-finding" is belied by the facts themselves, which show that TPPs did have enough information from ESI and other sources to respond in various ways to eliminate or mitigate any impact. For example, one day after receiving the ESI letter, the Vice

<sup>&</sup>lt;sup>10</sup> For example, plaintiffs refer to the ESI alert to its TPP clients as communicating the spread increase "in a neutral in fashion" (Pl. Reply Br. at 4, n.6), even though it is entitled "Urgent!" and advises the TPPs to take immediate action. In addition, plaintiffs argue that ESI's letter covered only "certain drugs" and the response by one TPP to ESI showed lack of recognition. (*Id.* at 11-12.) As is plain from the ESI letter, ESI advised that the increases were part of a new trend towards consistency in AWP-WAC ratios. As for lack of TPP recognition, plaintiffs can only make this assertion by ignoring the subsequent correspondence between ESI and its TPP clients showing that TPPs clearly recognized the import of ESI's urgent alert.

President of a TPP wrote to ESI asking to immediately take offsetting measures to counter the increase:

> Erin, I'd like to put some quantity limits in place where we have none but should and, make some of our existing edits more stringent. We'll need to start with our fully funded plans and move to the self-funded afterwards. I'd also like to try this in TennCare and see what the TC Solutions Unit will let us get away with. I'd like to move quickly on this. What are your recommendations?

(App. A ¶ 19, Schechter Sur. Decl. Ex. 24F, ESI-414-00004109.) Similar exchanges between ESI and its TPP clients, previously submitted with McKesson's class opposition papers, reveal that TPPs did act to eliminate the impact or to recoup the increased costs from the Spread Increase. (App. A ¶¶ 17-23.) And more of this type of evidence continues to be discovered.

For example, Promedica, another TPP client of ESI, recently produced documents revealing that all of the impact from the Spread Increase observed in 2002 had been recouped by Promedica as a result of concessions ESI made in its subsequent contracts across all of Promedica's reimbursed drugs, not just the drugs whose spreads had increased from 20% to 25%. (App. A ¶ 17, Schechter Sur. Decl. Ex. 29, PROMEDICA/NEC 00006-8.) ESI provided the cost recovery to its client "most likely by squeezing the pharmacies out of the margin they previously benefited from and moving some money around too." Id. at 00007. Thus, Dr. Hartman's bald assertion (Hartman Rebuttal Decl. ¶ 3) that even TPPs with knowledge of the Spread Increase were unable to negate the impact of higher AWPs (i.e., because "FDB merely flipped a computer switch that increased the spread" causing all TPPs to be "impacted and injured"), is flatly contradicted by what actually happened in the marketplace over the 3-1/2 year Class Period.11

<sup>&</sup>lt;sup>11</sup>Plaintiffs argue that offsets from new contract provisions and plan design changes that reduce or eliminate the impact of the Spread Increase to each plaintiff cannot be legally considered because of the "collateral source rule," which bars a tortfeasor from reducing its liability to the injured party by amounts the latter subsequently recovers from a third party. (Pl. Reply Br. at 13-15.) This rule is inapplicable here. RICO permits each directly injured party to recover to the full extent of its direct injury, but only to the extent of injuries actually sustained as measured at the time of adjudication. See, e.g., Bonilla v. Trebol Motors Corp., 150 F.3d 77, 87 (1st Cir. 1998); Commercial Union Assurance Co. v. Milken, 17 F.3d 608, 612 (2d Cir. 1994). Thus, if plaintiffs have recouped any increased costs, or another party has incurred the increased costs in the first instance as a result of plan changes to deductibles, drug exclusions, or generic caps, plaintiffs are not entitled to seek recovery of those costs.

Courts routinely reject "assumptions" of class-wide impact where, as here, the assumptions that plaintiffs' experts were asked to make were at odds with market realities. Sample v. Monsanto Co., 218 F.R.D. 644, 650 (E.D. Mo. 2003), aff'd sub nom. Plades v. Monsanto Co., 400 F.3d 562 (8th Cir. 2005) (rejecting plaintiffs' presumption of impact which did not consider whether the markets at issue actually operated in such a manner, and denying class certification of this price-fixing case as a result); see also In re Medical Waste Servs. Antitrust Litig., No. 2:04MD1546, 2006 WL 538927, (D. Utah March 3, 2006) (electining to certify a class where expert assumed class-wide impact, despite evidence to the contrary). This Court should do the same here.

### C. Dr. Hartman's Newly Created Regression Analysis Fails to Support His "Zero Knowledge — Zero Mitigation" Thesis.

To bolster his "findings" that TPPs were unaware of the Spread Increase, Dr. Hartman now provides an authoritative-looking regression analysis intended to prove that 'the trend in discounts and dispensing fees that started before the alleged scheme, continued in the exact same fashion after the scheme, with no evidence in measurable divergences during the period of the scheme." (Pl. Reply Br. at 13.) Thus, if the regression analysis actually supported this assertion, it would presumably negate the proposition that any TPPs knew of the Spread Increase and/or took any steps to negate or mitigate the effect of it. (Hartman Rebuttal Decl. ¶ 9 (figs. 1 a-b; Attach. E.). Dr. Willig demonstrates, however, that because of readily apparent flaws, the regression analysis in no way supports Dr. Hartman's "zero knowledge — zero mitigation" assertion. (Willig Rebuttal Decl. ¶ 53-63.)

First, Dr. Hartman's regression analysis focuses solely on discounts off AWP and dispensing fees, ignoring altogether all of the other means by which PBMs could and did pass on price-related benefits to TPPs during the Class Period. As one of the largest consultants to TPPs testified, one must look at the entire package of financial and non-financial terms to

<sup>&</sup>lt;sup>12</sup> These include financial term mechanisms, such as sharing manufacturer rebates and reducing acministrative fees, see Pharm. III at 72-73 & 94-95, as well as non-financial term mechanisms, like utilization management programs to lead patients to particular drugs and away from others, i.e., plan design adjustments. (See McKesson Opp'n at 12-16.)

determine the net drug cost to the TPP. (Schechter Sur. Decl. Ex. 27, Gibbs Dep. 87:5-88:23.) Dr. Hartman failed to do so. (See Willig Rebuttal Decl. ¶ 54.)

Moreover, Dr. Hartman measured the trend in AWP discounts and dispersing fees only against time, including the time covered by the Class Period. Thus, his regression analysis stands for the unremarkable and uncontested proposition that the percentage discount off AWP continued to increase over time. (Id.  $\P$  55.) What Dr. Hartman's regression fails to show is why the AWP discounts increased over time: was it simply the passage of time, or something else, such as increases in AWP? (Id.  $\P$  56.) Thus, the analysis provides no support whatsoever for Dr. Hartman's lynchpin assumption that discounts did not increase in response to the Spread Increase. (Id. ¶ 53.) Dr. Hartman's regressions cannot, therefore, support his "zero knowledge — zero mitigation" position.

To address specifically whether discounts off AWP increased in response to the Spread Increase, Dr. Willig constructed his own econometric model. Dr. Willig's model evaluates whether AWP inflation or a simple time trend better explains the changes in discounts and dispensing fees. Dr. Willig also differentiates in his model between AWP inflation caused by underlying WAC increases (general inflation) and overall AWP inflation including inflation caused by the Spread Increase. (Id. ¶¶ 53, 57, 61.)

Dr. Willig's findings contradict Dr. Hartman's position that discounts increased in response to general inflation in AWPs but not in response to inflation in AWPs caused by the Spread Increase. (Id. ¶ 62.) Specifically, the regression analysis shows that the increasing discounts off AWP during the Class Period are better explained by overall AWP inflation, rather than either a simple time trend or AWP inflation caused by underlying WAC inflation. (Id. ¶¶ 53, 62.) Dr. Willig's regression analysis also confirms that to the extent the Spread Increase caused AWPs to increase, it caused responses that mitigated the impact of growth in AWP. (Id. ¶63) Looked at either way, Dr. Hartman's zero mitigation thesis is plainly untenable, as demonstrated by a properly prepared regression analysis.

#### D. Plaintiffs Wrongfully Seek the Court's Merits Determination on Knowledge and Class-Wide Impact.

In order to escape the disabling consequences of TPP knowledge to their class motion, plaintiffs, in effect, ask the Court to make a factual determination that no TPP knew of the Spread Increase and/or took any steps to negate or mitigate any resulting increased costs. As shown, plaintiffs rely on Dr. Hartman's regression analysis, new declarations of the named plaintiffs, and denigration of McKesson's contrary evidence. Essentially, plaintiffs are seeking summary judgment as their only means to avoid Rule 23(b)(3) consequences on the fact issues of TPP knowledge and response. Case law, however, is decidedly to the contrary.

Thus, both the Supreme Court and the First Circuit have prohibited precisely this type of accelerated merits determination in a Rule 23 proceeding, citing the prejudice that would result from making ultimate findings of fact on the limited record available for class certification. See Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1974) ("[A] preliminary determination of the merits may result in substantial prejudice to a defendant, since of necessity it is not accompanied by the traditional rules and procedures applicable to civil trials ... "); In re Polymedica Corp. Sec. Litig., 432 F.3d 1, 19 (1st Cir. 2005) (cautioning against "turning the class-certification proceeding into a mini-trial on the merits, which must not happen."). 13 The Supreme Court's caution in Eisen is particularly applicable here where discovery is still ongoing, and not a single PBM has yet been deposed.

What all this shows is that absent an unwarranted merits determination in plaintiffs' favor, disputed issues of fact regarding knowledge and response by TPPs to the Spread Increase

<sup>&</sup>lt;sup>13</sup> Distinguishable are Rule 23 cases where a court will make an empirical determination regarding whether the market for a security is "efficient" for purposes of the fraud on the market presumption of reliance in security cases. See, e.g., In re Initial Public Offering Sec. Litig., 431 F.3d 24 (2d Cir. 2006). That empirical inquiry is entirely distinct from the inquiry into individual TPPs' knowledge and responses that plaintiffs ask the Court to resolve here. The former involves general evidence of market efficiency, an issue unquestionably common to the putative class. By contrast, the fact issues at stake here involve individual issues of knowledge, responsiveness and negotiating posture, among others — the very issues that vary among the individual class members.

present overwhelmingly individual issues of material fact, defeating certification under Rule 23(b)(3).<sup>14</sup>

# II. DR. HARTMAN'S FORMULAIC METHODOLOGY FOR CLASS-WIDE IMPACT AND DAMAGES DOES NOT OVERCOME THE PREDOMINANCE OF INDIVIDUAL ISSUES.

From the outset, plaintiffs have maintained that Dr. Hartman had developed a formulaic methodology establishing uniform class-wide impact and damages due to the Spread Increase and increased AWPs. (Pl. July 17. Br. at 2; Pl. Am. Br. at 2-3.) Stripped to its basics, Dr. Hartman's formulaic methodology, by his own admission, is nothing more than a simple mathematical calculation that multiplies the AWP of each drug listed in Exhibit A to the Complaint by the 5% increase (Schechter Sur. Decl. Ex. 25, Hartman Dep. 369:8-370:12), and assumes 100% pass-through of increased drug costs due to the 5% Spread Increase. In so doing, Dr. Hartman assumes zero knowledge and zero mitigation by TPPs.

### A. Dr. Hartman's Assumption of Zero Mitigation Is Contradicted by the Facts.

As demonstrated in Part I, Dr. Hartman's assumption of zero mitigation cannot be squared with the facts. (*See* App. A.) To support his assumption, he asserts no TPP knew of the Spread Increase, but the evidence plainly shows that they did. He maintains that no TPP mitigated the effect of increased AWPs arising from the Spread Increase, but they did. He opines that it would be "economically irrational" for PBMs to advise their TPP clients of the Spread Increase (Hartman Rebuttal Decl., Attach. C, ¶ 7 & n.10), but they did. For these reasons alone, the Hartman formulaic methodology is simply unsupportable as a matter of fact.

<sup>&</sup>lt;sup>14</sup> Lacking any legitimate basis to support class certification, plaintiffs attempt rather transparently to divert attention from Rule 23 requirements to their highly selective and out-of-context quotations of McKesson documents. (Pl. Reply Br. at 5-10.) Suffice to say, both McKesson and FDB have steadfastly denied any "scheme" as McKesson will demonstrate at the appropriate time.

### B. Dr. Hartman's Assumption Is Also at Odds with Conventional Economic Theory.

In his new Rebuttal Declaration, Dr. Hartman now exposes another fallacy underlying his zero mitigation assumption. Specifically, he now discloses that his assumption is based upon a critical distinction: that when AWPs increased due to "normal market forces," TPPs *did* obtain offsetting increased discounts from PBMs. But, when AWPs increased due to the Spread Increase, there was zero offsetting mitigation. (Hartman Rebuttal Decl. ¶¶ 6-7.) As Dr. Willig's Rebuttal Declaration makes clear, the distinction drawn by Dr. Hartman between market and non-market forces causing increased AWPs is utterly fallacious. (Willig Rebuttal Decl. ¶¶ 7-13.) Not surprisingly, Dr. Hartman offers no economic justification for it in his Rebuttal Declaration.

Actually, when AWPs are increased without a corresponding increase in cost (WAC), there is even greater reason to expect that TPPs will mitigate or even negate the increased cost. With a supposedly "artificial" increase in published AWPs, *i.e.*, artificially increased profits, TPPs have an enhanced ability to extract concessions from PBMs to mitigate the increased cost from higher AWPs. (Willig Rebuttal Decl. ¶¶ 14-16, 53.) Indeed, PBM competition for TPP business is one of the bases for Dr. Berndt's rejection of Dr. Hartman's formulaic methodology in MDL. (Schechter Decl. Ex. 2A, Berndt Rep. ¶ 206.)

In addition, Dr. Hartman testified that TPPs focus primarily on AWPs, not on WAC-AWP spreads (or even WACs). (Schechter Sur. Decl. Ex. 25, Hartman Dep. 62:15-63:19, 71:9-73:11.) Thus, according to Dr. Hartman, TPPs would not know why AWPs increased. It follows that TPPs will treat increased AWPs alike in their efforts to mitigate or negate their effect. (Willig Rebuttal Decl. ¶¶ 14-16, 53.)

### C. Dr. Hartman's Assumption Is Contradicted by Plaintiff's' Co-Expert, Susan Hayes.

In plaintiffs' original motion for class certification, plaintiffs relied extensively on the expert declarations of both Susan Hayes and Dr. Hartman for the same class-wide impact and damage thesis. (Pl. July 17 Br. at 2 & n.2, 3, 4 & n.8, 5 & n.9-10, 14 & n.24, 19 & n.29.) As plaintiffs' brief noted:

Plaintiffs have submitted the Declarations of Raymond S. Hartman and Susan Hayes in Support of their motion for Certification of the Class. Both experts explain that class-wide data is available to demonstrate that Defendants' unlawful scheme injured all Class members.

(*Id.* at 2.)

Unlike Dr. Hartman, Ms. Hayes was held out as having 19 years of real-life, hands-on experience with AWP, WAC, and AWP-WAC spreads, as an auditor/consultant with a client list including all manner of TPPs, from Fortune 500 companies and insurance giants to small unions and employer groups. (Hayes Decl. ¶¶ 1-2, curriculum vitae.) Together with others in her own company, she had performed or participated in approximately 450 pharmacy claims audits involving AWP and WAC computations and concepts. (*Id.* ¶ 1.) Similarly, at her deposition in this case, Ms. Hayes testified to having hands-on, broad-based experience with TPP drug reimbursements, discounts, and related industry practices. (Hayes Dep. 70:7-15, 151:13-152:12, 182:5-20.)

As noted in McKesson's Opposition, Ms. Hayes testified, directly contrary to Dr. Hartman, that during the Class Period, discounts off AWP did increase substantially, and that she attributed those increases to the 5% Spread Increase. (See Opp'n. at 6-7). Nowhere in their reply do plaintiffs address the directly conflicting views of their two designated experts. Ignoring this conflict will not make it disappear. To be sure, it appears that Ms. Hayes has since been fired. But her testimony under oath remains still another reason for rejecting Dr. Hartman's formulaic methodology and its zero mitigation assumption.

#### D. Dr. Hartman's Assumption Is Opposed by Dr. Berndt.

Precisely the same is true of Dr. Berndt, whose opinions also directly conflict with Dr. Hartman. (See Opp'n at 3-4.) In Pharm. III, Dr. Berndt opined that if self-administered AWPs were artificially inflated, class-wide injury and damages would not follow because of intense competition among PBMs. (Schechter Decl. Ex. 2A, Berndt Rep. ¶ 206.) According to Dr. Berndt, the assumption underlying Dr. Hartman's class-wide impact and damage position — that competition among PBMs "is not effective" — is wrong. (Id. ¶ 205.)

At his deposition in this case, Dr. Hartman testified he was unable to contradict Dr. Berndt's conclusion. <sup>15</sup> Now, however, Dr. Hartman quite clearly rejects Dr. Berndt's conclusion regarding PBM competition, and concludes instead that it would be "economically irrational" for PBMs to advise TPP clients of the Spread Increase. (Hartman Rebuttal Decl. Attach. C, ¶ 7 & n.10.)<sup>16</sup>

In *Pharm. III*, this Court decided it was unnecessary to decide which economist was correct, since denial of certification was otherwise warranted. *Pharm. III* at 94. The same is true here. Still, evidence produced in this case to date regarding PBM competition certainly demonstrates Dr. Berndt to be correct.

### E. Dr. Hartman Has Not Proposed Any Method for Calculating Consumer Damages.

Plaintiffs and their expert, Dr. Hartman, have yet to propose a means of calculating damages to the putative consumer class – whose damages are every bit as complicated as those for their TPPs. Rather, plaintiffs simply assert that Dr. Hartman would apply a "similar" methodology to the one proposed in the MDL. (Pl. Am. Br. at 15 & n.22.) This is apparently news to Dr. Hartman, who testified at deposition that no consumer class could exist. And not one of the three declarations he submitted in support of class certification contains a formulaic methodology for calculating consumer damages — either in the aggregate, or individually among putative class members. (Hartman July 17 Decl.; Hartman Decl.; Hartman Rebuttal Decl.) Accordingly, plaintiffs have failed to carry their burden under Rule 23(b)(3).

(Schechter Sur. Decl. Ex. 25, Hartman Dep. 212:19-213:14.)

<sup>&</sup>lt;sup>15</sup> Specifically, Dr. Hartman testified that he had "not done a sufficient analysis" to contradict Dr. Berndt's conclusions regarding PBM competition. (Schechter Decl. Ex. 8A, Hartman Dep. 198:2-199:16.)

<sup>&</sup>lt;sup>16</sup>Dr. Hartman's disagreement with Dr. Berndt perhaps explains the determined effort by Dr. Hartman to explain away ESI's providing exactly that information to its TPP clients.

<sup>&</sup>lt;sup>17</sup> The following exchange illustrates Dr. Hartman's understanding of the consumer class:

Q. Why didn't you take into account copays?

A. Because I was — because the copays, for the most part, are unrelated to the effects of the scheme.

Q. How do you know that they're unrelated?

A. Because everything I've seen tells me that the — for this set of drugs, copays are flat for the self-administered branded drugs.

Certification of the consumer class here, like the consumer class for self-administered drugs in *Pharm. III*, should be denied. <sup>18</sup>

#### III. PHARM. III COMPELS DENIAL OF CLASS CERTIFICATION.

In *Pharm. III*, the Court denied class certification in an action brought against drug manufacturers by these same TPPs and consumers who also alleged RICO and state law violations relating to claimed fraudulent AWP spreads for self-administered drugs. In the AWP MDL, plaintiffs claimed that, at the direction of defendants, FDB and others published artificially high AWPs for some of the same self-administered drugs during part of the same class period alleged here. Moreover, in the AWP MDL, as here, the same plaintiffs' counsel "rel[ied] heavily" upon Dr. Hartman's formulaic methodology for computing class-wide injury and damages to overcome predominantly individual issues under Rule 23(b)(3). *Pharm. III* at 87. While there are some factual differences between *Pharm. III* and this case, the two grounds upon which the Court denied class certification in *Pharm. III* are equally applicable here.

A. As in *Pharm. III*, Individual Issues Involving the Reimbursement Transactions for Self-Administered Drugs Preclude Class Certification.

To begin with, in *Pharm. III* the Court recognized that when it comes to the distribution of and reimbursement for self-administered drugs (as opposed to physician-administered drugs) PBMs play a central role. *Id.* at 71 (PBMs "are the 800-pound gorillas of pharmaceutical reimbursement"). They serve as the middleman assisting TPPs in implementing their drug prescription programs. *Id.* The contracts between TPPs and the PBMs tend to be "highly individualized." *Id.* at 72. Accordingly, to determine claimed impact and damages among the

In Pharm. III, while certification of a consumer class for self-administered drugs was denied, certification of a class of consumers who paid copays under Medicare Part B, was granted. 230 F.R.D. at 96. The Medicare consumer class is markedly different from the self-administered consumer class alleged here. In the Medicare Part B context, the damage calculation for consumers was straightforward because Medicare Part B copay amounts are uniform, as determined by statute and regulation. By contrast, for self-administered drugs, consumers stand downstream from their TPPs, so the dollar amounts of their percentage copays vary TPP by TPP. Thus, all of the individual issues precluding calculation of TPP impact and damages on a class-wide basis likewise apply to the alleged consumer class in this case.

11,000-plus TPPs would require examination of the "contractual relationship between each TPP and each PBM." *Id.* at 95. More than that:

There are also different levels of sophistication and knowledge among the TPPs. Because of the variability of TPPs' contracts with PBMs, plaintiffs are unable to show that each TPP class member paid more than it would have in the absence of the fraud via common proof.

Id.

The particular impact-damage issue defeating certification in *Pharm. III* was whether and to what extent PBMs passed manufacturer rebates through to TPPs. *Id.* at 94-95. This case likewise involves the same question of pass-throughs by PBMs to TPPs of manufacturer rebates, but a great deal more as well. For, as shown in Parts I and II above, the clear-cut issue presented in this case is the extent to which, in response to higher AWPs arising from the Spread Increase, PBMs "passed through" to their TPP clients a variety of price-related benefits including not only manufacturers rebates but also larger AWP discounts, lower dispensing fees, lower administrative expenses, as well as other cost-lowering benefits.

Regarding rebates, plaintiffs do not dispute that during the Class Period there were manufacturer rebates to PBMs calculated as a percentage of AWP published by FDB. (Proffer ¶ 25; see also Schechter Sur. Decl. Exs. 23, 30.) As AWPs increased, PBMs received correspondingly increased rebates. Whether and to what extent PBMs passed these additional rebates on to TPPs will involve all of the same individual issues that the Court found disabling in *Pharm. III. Id.* at 94-95. <sup>19</sup>

Pointedly, the claims in this case implicate far more than just rebate pass-throughs. Specifically, plaintiffs have argued that the primary beneficiaries of the alleged scheme were retail pharmacies who received higher reimbursements due to higher AWPs. (SAC ¶ 12.) Quite

<sup>&</sup>lt;sup>19</sup> Just as in *Pharm. III* (*id.* at 94-95), Dr. Hartman maintains here that he can develop a methodology to calculate rebates actually paid to TPPs. (*See* Hartman Decl. ¶¶ 24-25.) However, just as in *Pharm. III* such aggregate calculations are "unsatisfactory" because they do not measure the net AWP reimbursements paid by TPPs, *i.e.*, net of rebates received. *Pharm. III.* at 95.

clearly, PBMs would have squeezed those profits out of retailers in their networks through recontracting. As a recently produced document confirms, as a result of the Spread Increase, in 2002 ESI was able to "reduce the impact" on TPPs "by squeezing the pharmacies out of the margin they previously benefited from . . ." (App. A at ¶ 17 (PROMEDICA/NEC 00006-7).) Like ESI, Caremark, another one of the three largest PBMs, also took the FDB Spread Increase into account in negotiating contracts with retail pharmacies during the Class Period. (Schechter Decl. Ex. 4A, Madsen Decl. ¶ 3.)

The individual issue here, as in *Pharm. III*, is whether and to what extent PBMs passed on their profits to their clients, as ESI apparently did to Promedica in 2002. Again, just as in *Pharm. III*, that inquiry will necessarily involve examining, on an individual TPP-PBM basis over a 3-1/2 year period, the financial arrangements and transactions between each TPP and PBM. In the ESI example described above, the profits were passed through to the TPP retroactively when the next contract was entered into. Since the TPP-PBM contracts are generally amendable during their term (Proffer ¶ 26-28), such pass-throughs could have occurred at any time, thereby enabling TPPs to recoup any loss caused by the Spread Increase. What all of this shows is that individual issues preclude certification for the same reasons involved in *Pharm. III*.

Nor, as in *Pharm. III*, may plaintiffs overcome these individual fact issues by relying on horizontal antitrust price-fixing cases for the proposition that uniform impact and damages must be presumed on a class-wide basis. (Pl. Reply Br. at 14-15.) This Court rejected these cases in *Pharm. III* because, among other reasons, the TPPs were able to take steps to avoid the impact of alleged secret rebates whereas in horizontal price fixes impact is unavoidable. *Pharm. III.* at 94 ("Payors could simply switch to a competitor PBM if they were not receiving competitive prices."). These same principles apply here because the intense competition among PBMs—as

already shown — could mitigate or entirely negate the effects of the Spread Increase on TPPs, and consequently on their members.<sup>20</sup>

More comparable are indirect-purchaser antitrust cases, where courts have long recognized the functional difficulties in adjudicating the pass-on of increased costs from one buyer to the next. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720, 737 (1977) (refusing to allow indirect purchasers to sue for antitrust violations because it would "transform treble-damages actions into massive efforts to apportion the recovery among all potential plaintiffs that could have absorbed part of the overcharge -- from direct purchasers to middlemen to ultimate consumers."). The Supreme Court has recognized these concerns in the RICO centext as well. *See Holmes v. Sec. Investor Prot. Corp.*, 503 U.S. 258, 268-69 (1992) ("quite apart from problems of proving factual causation, recognizing claims of the indirectly injured would force courts to adopt complicated rules apportioning damages among plaintiffs removed at different levels of injury from the violative acts, to obviate the risk of multiple recoveries.").

These functional difficulties are present here, as the Court must determine how much, if any, of the increased cost from higher AWPs was passed on from pharmacies to PBMs, from PBMs to TPPs, and from TPPs to their members, taking into account the offsetting impact of manufacturer rebates, AWP discounts, and other price-related terms. *Cf. Pharm. III* at 72-73 (explaining steps in a typical manufacturer-pharmacy-PBM-TPP transaction). This is a predominantly individual issue and explains cases denying class certification in indirect purchaser class actions. *See, e.g., In re Methionine Antitrust Litig.*, 204 F.R.D. 161, 166-67 (N.D. Cal. 2001) (denying certification of a class that included indirect purchaser/resellers where "some of the class members ... may not have been injured by the antitrust conspiracy because

<sup>&</sup>lt;sup>20</sup> Plaintiffs are also incorrect in their assertion at page 18 of their Reply Brief that Dr. Hartman's formulaic methodology follows the standard approach that economists use in price fixing cases or cases involving the manipulation of baseline prices. As Dr. Willig explains, Dr. Hartman's formula is a simple calculation without the standard statistical estimation or testing of what prices would have been in the "but for" world. (*See* Willig Rebuttal Decl. ¶ 13.)

the overcharge was not passed along or because the class member itself passed along the full amount of the overcharge to its customers.").<sup>21</sup>

## B. As in *Pharm. III*, Inflated Self-Administered Drug Claims Present Insurmountable Manageability Issues.

The presence of predominately individual issues is not the only ground upon which the court denied class certification in *Pharm. III.* As an alternative ground for denying certification, the Court looked to another "key factor" under Rule 23(b)(3), "manageability, which focuses on pragmatic concerns." *Id.* at 90. Because of the problems presented by individual damage trials, as well as the application of the laws of the states where plaintiffs reside, the Court found that the lack of manageability of a class trial precluded certification of both the TPP and the consumer classes involving self-administered drugs. The same is true here.

### 1. Plaintiffs' Aggregate Damages Model Does Not Preclude the Individual Damage Trials Required by This Case.

In the AWP MDL, the Court ruled that "even if Hartman's methodology could be fine-tuned, the class of all 11,000 TPPs is not manageable." *Id.* at 95. The court emphasized that:

Holding 11,000 individual damages trials . . . is a management nightmare, and class certification is not a superior method for resolving the fraud claims of each TPP.

Id.

Exactly the same is true here, as Dr. Hartman's formulaic methodology does not eliminate the need for individual damage trials. As in *Pharm. III*, the extent to which manufacturer rebates were shared with each TPP would have to be examined to determine if AWP-based rebates offset the growth in AWPs as a result of the Spread Increase. In addition,

<sup>&</sup>lt;sup>21</sup> See also Melnick v. Microsoft Corp., No. CV-99-709, CV-99-752, 2001 WL 1012261, at \*7 (Me. Super. Ct. Aug. 24, 2001) (noting that while the existence of a price-fixing conspiracy may logically lead to the conclusion that the direct purchaser has been harmed, "no such conclusion logically follows without specific proof tracing" that the indirect purchaser has been injured); see also Sugai Prods., Inc. v. Kona Kai Farms, Inc., Civ. No 97-00043, 1997 U.S. Dist. LEXIS 21503, at \*40 (D. Haw. Nov. 19, 1997); In re Brand Name Prescription Erugs Antitrust Litig., No. 94 C 897, MDL 997, 1994 U.S. Dist. LEXIS 16658, at \*\*17-18 (N.D. Ill. Nov. 15, 1994); Karofsky v. Abbott Labs., No. CV-95-1009, 1997 Me. Super. LEXIS 316, at \*48 (Me. Super. Ct. Oct. 15, 1997); Wood v. Abbott Labs., No. 96-512561-CZ, 1997 WL 824019, at \*2 (Mich. Cir. Ct., Sep. 11, 1997); Keating v. Philip Morris, Inc., 417 N.W.2d 132, 137 (Minn. Ct. App. 1987).

each trial would have to determine, for each TPP, whether the TPP was able to achieve greater concessions from its PBM (e.g., by recontracting with steeper AWP discounts and/or increased rebate pass-throughs) as a result of the Spread Increase such that any damages from increased AWPs would be eliminated, mitigated, or recouped for itself and for its members. Likewise, the individual plan designs for each TPP, and for each TPP member in the consumer class alleged, would have to be analyzed to determine whether cost-shifting provisions, such as capped reimbursements, excluded drugs, or changes to copays, altered the impact from the Spread Increase. Moreover, even if Dr. Hartman's formulaic methodology were admissible, McKesson would still be entitled to show — TPP by TPP — that the TPP was aware of the Spread Increase and took steps to eliminate entirely or, at the least, to mitigate any impact of higher AWPs.

### 2. The Variability in State Laws Also Renders the Proposed Classes Unmanageable

The proposed class is made even more unmanageable because, as in *Pharm. III*, the law of the class members' home states should govern plaintiffs' state law claims. In *Pharm. III*, the Court conducted a thorough analysis of Massachusetts choice of law rules and applied the "functional approach" of Restatement Section 148(2). *Pharm. III* at 82 (citations omitted). The court relied on three factors from Section 148(2), and noted that "the place of action in reliance" was the most important. *Id.* at 83. Under that analysis, the Court held that the laws of the states in which class members purportedly relied upon AWPs control. *Id.* Because plaintiffs here are likewise seeking recovery on claims of fraudulently inflated AWPs under state consumer protection law, *Pharm. III* applies.

In their Reply, plaintiffs claim that the "choice of law issue in this case is substantially different." (Pl. Reply Br. at 21.) Yet the only distinction between the two cases that plaintiffs make is the existence in California of FDB's database containing AWPs. (Pl. Rep. Br. at 21,

<sup>&</sup>lt;sup>22</sup> McKesson previously filed an Opposition to Plaintiffs' Motion for a Determination of Controlling State Law, [Docket No. 189]. On February 1, 2007, the Court ruled that plaintiffs' motion was unnecessary and that it would determine choice of law in the context of class certification. Plaintiffs re-briefed the issue in their reply on class certification, and McKesson hereby responds to that brief.

n.51.)<sup>23</sup> The data is not a "tangible thing" located in California, nor is it relevant to the choice of law analysis, as plaintiffs contend. The AWP data is an electronic database that exists wherever it is disseminated, including to the TPPs in their home states. See Clark v. Experian Info. Solutions, Inc., No. 03 C 7882, 2005 U.S. Dist. LEXIS 8243, at \*\*14-16 (N.D. III. Apr. 26, 2005) (in assessing choice of law question, court expresses doubt that data residing on defendant's computer in California could be considered "tangible."). In any event, the database is not chattel that was bought or sold, and thus its location is not a factor in the analysis. See Restatement § 148 cmt. i ("contact is of particular importance when the subject of the transaction is land.").

Pharm. III likewise forecloses plaintiffs' argument that California law best effectuates the interests of the states in protecting their residents from deceptive practices. (Pl. Reply Br. at 24.) To begin with, the interests of the states do not factor into the Restatement Section 148(2) analysis at all. See Pharm. III at 83. Moreover, plaintiffs mischaracterize California law as providing equal or greater protection than comparable laws of other states. This is not the case under the Unfair Competition Law (UCL), or under the Consumer Legal Remedies Act (CLRA), the two California statutes plaintiffs invoke in this case.

The UCL, Cal. Bus. & Prof. Code §§ 17200-17210, was amended in 2004 to require a showing of actual injury, reliance, and causation. See Brown v. Bank of Am., No. 05-10713-PBS, 2006 U.S. Dist. Lexis 76418, at \*\*16-17 (D. Mass. Oct. 17, 2006) (Saris, J.) (noting that "California's recently amended consumer protection statute" requires a showing of "causation" and "injury in fact" to prevent uninjured private persons from suing."). Plaintiffs' citation to pre-2004 cases is thus unavailing. California law now offers less protection than, for example, the laws of 46 other states that do not require a showing of reliance under the state's consumer protection statutes. (See Berman Decl., Ex. 53A.) In addition, California's consumer protection

<sup>&</sup>lt;sup>23</sup> Disregarding Pharm. III at 83, plaintiffs invoke the general torts section of the Restatement (§145) to support their argument that the location of defendants' misconduct should apply. (Pl. Reply Br. at 21-22 & n.53.) It is only where the injury suffered is the loss of customers or trade --- as in a business tort --- that the location of a defendants' misconduct takes on greater significance. Restatement § 145 cmt. f.

laws place limits on restitution and its unfair competition and false advertising statutes do not provide for damages, punitive damages, or attorneys' fees. Cal. Bus. & Prof. Code §§ 17203, 17536; Cel-Tech Commc'ns Inc. v. Los Angeles Cellular Tel. Co., 973 P.2d 527, 539 (Cal. 1999).

The CLRA likewise requires proof of causation, but it also limits recovery to purchases primarily for personal, family, or household purposes. Cal. Civ. Code §§ 1761(a) & (d), 1770(a), 1780(a); Wilens v. TD Waterhouse Group, Inc., 120 Cal. App. 4th 746, 754 (Cal. Ct. App. 2003). Significantly, plaintiffs have failed to address the fact that the CLRA's standing limitations would preclude TPPs from bringing claims. By contrast, other states allow "any person" to bring an action, including natural, corporate, or otherwise. Plaintiffs cannot, therefore, claim that California's laws are sufficiently "compatible with the most protective state unfair competition and false advertising laws" such that no conflict or only a "false conflict" exists with those states' laws. (Pl. Reply Br. at 24). 25

Finally, contrary to plaintiffs' assertion, *id.*, California's interest under its consumer protection laws is in "compensating consumers, not policing corporate conduct." *Pharm. III* at 83, *citing Relafen*, 221 F.R.D. at 227. California's consumer protection laws, like those of other states, are "designed to protect the residents of the states in which the statutes are promulgated." *Id.*, *citing Lyon v. Caterpillar, Inc.*, 194 F.R.D. 206. 216 (E.D. Pa. 2000). There is thus no basis to apply California law to the alleged nationwide classes, and the holding in *Pharm. III* should apply to this case.

<sup>&</sup>lt;sup>24</sup> See, e.g., N.J. Stat. Ann. §§ 56:8-1, 8-19 (Consumer Fraud Act); Idaho Code Ann. §§ 48-602(2),608 (Consumer Protection Act); N.D. Cent. Code §§ 51-15-01(4), 02, 09 (Unlawful Sales or Advertising Practices).

<sup>&</sup>lt;sup>25</sup> Plaintiffs offer the additional argument that California law does not present a conflict because "many" of the class members' home states of residence do not allow their residents to enforce consumer protection statutes as a class. *Id.* But this Court observed in *Pharm. III* that seven states — not "many" — prohibit such class actions. *Pharm. III* at 84.

<sup>&</sup>lt;sup>26</sup> As this Court noted in *Pharm. III* that "[s]tate consumer-protection laws vary considerably, and courts must respect these differences rather than apply one state's law to sales in other states with different rules." *Pharm. III* at 83, citing *Relafen*, 221 F.R.D. at 277-78.

#### CONCLUSION

In sum, for the same reasons of individual issue predominance and lack of manageability that led the Court to deny certification in *Pharm. III*, McKesson respectfully submits that plaintiffs' motion to certify must be denied.

Respectfully submitted,

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#### CERTIFICATE OF SERVICE

I hereby certify that a true copy of the above document was served upon the attorney of record for each other party through the Court's electronic filing service on May 7, 2007.

/s/ Lori A. Schechter
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#### APPENDIX A

### A SAMPLE OF EVIDENCE DEMONSTRATING THAT TPPS WERE AWARE OF AND RESPONDED TO THE SPREAD INCREASE.

- A. TPPs Learned of the Increase in FDB's AWP-WAC Ratios from PBMs Who Were in a Position to Extract from Retail Pharmacies and Share with TPPs Any Resulting Profits.
- 1. For example, as early as January 2002, Express Scripts ("ESI") learned that the AWPs for specific drugs had increased without a corresponding increase in the WACs for those drugs. (Schechter Decl. Ex. 6M, ESI-414-00001807; Proffer ¶ 8.)
- 2. As it became apparent that FDB had increased the ratio between its published AWPs and WACs, ESI initiated an internal review to compare the AWP information published by the three main publishers, FDB, Medispan, and Redbook. (*Id.* Exs. 6L, 6M, ESI-414-00001805-1808; Proffer ¶ 9.) ESI's internal review indicated that as of March 2002, 830 NDCs had been affected, with the AWPs for 650 NDCs going up and the remaining 180 going down. (*Id.* Ex. 6H, ESI-414-00001762; Proffer ¶ 9.)
- 3. On or before March 11, 2002, Kay Morgan, an FDB employee, told ESI that "it is very possible that we will see more vendors moved to the WAC plus 25% method of creating AWP." (*Id.* Ex. 6M, ESI-414-00001807; Proffer ¶ 10.)
- 4. On March 15, 2002, ESI personnel spoke with FDB personnel by phone. FDB explained that AWP increases would happen with the next increase in WAC: "If the survey shows that the AWP should be moved to WAC plus 25% then it will be moved at the next WAC increase.... AWP adjustments are made when a price increase occurs." (*Id.* Ex. 6K, ESI-414-00001802; Proffer ¶ 11.) First Databank said ESI "could release this information to anyone [it] wanted to." (*Id.*) An internal ESI memorandum prepared after the call with FDB states: "According to First Data Bank, our pricing service, the recent adjustments were made to reflect a more consistent relationship between WAC and AWP across branded products." (*Id.* Ex. 6N, ESI-414-00001827; Proffer ¶ 11.)

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- 5. In turn, ESI personnel understood that all AWPs would eventually be moved to WAC + 25%. An internal email from March 22, 2002 states: "The analysis from Dec to Feb of last year has been completed. This study has shown that the increase is approximately 1% higher in 2002 than it was in 2001. I believe this confirms what FDB had to say on the conference call FRiday [sic] that these type of changes primarily started in January of 2002. My guess is that we will see them continue to be adjusted until all manufacturers and drugs are at the WAC + 25%range." (Id. Ex. 6G, ESI-414-00001760 (emphasis added); Proffer ¶ 12.)
- ESI anticipated in March 2002 that it would have to negotiate steeper discounts to accommodate the AWP increases: "If the AWP becomes an unreliable factor, a pricing paradigm shift may be required. ." (Id. Ex. 6H, ESI-414-00001762; Proffer ¶ 13.)
- 7. After ESI learned about the increases in AWP-WAC ratios, ESI disseminated a client alert, entitled "Average Wholesale Price Increases," for distribution to clients beginning in April 2002. The alert states:

Pharmaceutical manufacturers make price changes throughout the year. As we have documented in Express Scripts' annual Drug Trend Report, for the last four years the average increase in Average Wholesale Price ("AWP") has exceeded 5%. The first wave of price increases typically take place in the January through February timeframe. Over the last couple of years these increases have averaged 1 to 1.5%. This year, however, the increase for this period January through February timeframe is closer to 2.5%. The increase for this period also includes an adjustment to increase the difference between wholesale acquisition cost ("WAC") and AWP for certain drugs. In other words, a little less than half of the total increase is due to AWP increases that are in excess of the corresponding increase in WAC.

Upon our inquiry to our pricing service, First Data Bank (the industry's primary source for AWP information), the recent AWP adjustments were made to establish a more consistent relationship with WAC. As this trend indicates, it is more important now than ever to put cost management strategies in place.

(*Id.* Ex. 6F, ESI-414-00001754; Proffer ¶ 14.)

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- 8. ESI's client alert was sent to TPPs. (Id. Exs. 6R, 6T, ESI-414-00003693-94, 3780-84). In some cases, the alert was sent beneath a headline indicating "Urgent! Emerging Therapeutics Issue Communication." (Id. Ex. 6R, ESI-414-00003694; Proffer ¶ 15.)
- 9. ESI received follow up inquiries from several clients regarding this notice. Some clients responded requesting additional information to assess the impact of these changes. (Id. Ex. 6B, Macinski Decl. ¶ 6; Proffer ¶ 16.)
- 10. In March 2002, ESI noted that "[a]t this point several of the CPMs have been told versions of this information by pharma reps . . . . It is only a matter of time before this becomes widely known by our clients since pharma is openly discussing this with them." (Id. Ex. 6J, ESI-414-00001794; Proffer ¶ 17.)
  - B. TPPs Also Learned of the Increases in the AWP-WAC Ratio from Consultants, Auditors, and Industry Participants.
- 11. Peabody Energy Corporation, an employer-plan TPP, learned that FDB's AWPs were higher than Redbook's AWPs from its claims auditor, KPMG, during an audit of Medco's administration of Peabody's 2001-2002 claims. The audit report states: "KPMG reviewed the First DataBank and Red Book WAC and AWP unit prices. The AWP unit prices were usually a 25% markup over WAC. There were some cases the markup was 20%. For 12 out of the top 30 mail order NDCs, the FDB markup over WAC was 25% while the Red Book markup over WAC was 20%." (Id. Ex. 14A, KPMG 0305-0312; Proffer ¶ 19.)
- 12. Humana, another TPP, learned from its claims processor, Argus Health Systems, that FDB's AWPs were unusually higher than the AWPs published by Redbook. (Id. Ex. 12A, Fleming Dep. 158:13-160:11-15; Proffer ¶ 20.)
  - C. TPPs Learned of or Obtained Information about Increases in the AWP-WAC Ratio on their Own.
- 13. , a TPP, noticed that its rebates spiked in January 2002 and heard about the AWP increase "from more than one pharma company." In March 2002, after confirming the increases in AWP-WAC ratios with the drug manufacturer AstraZeneca, it alerted its PBM, ESI,

of the unusual increase in AWPs and pressured ESI to strategize cost control measures to address this increase. (*Id.* Ex. 6J, ESI-414-00001794; Proffer ¶ 21.)

- 14. Some TPPs, particularly large and sophisticated TPPs, subscribed to FDB and therefore received WAC and AWP pricing information directly from FDB. These include: Aetna (*Id.* Ex. 1A, Jackson Dep. 188:2-7), Blue Cross Blue Shield of Montana (*Id.* Ex. 3A, Wong MDL Dep. 17:19-18:6), Humana Inc. (*Id.* Ex. 12B, Fleming MDL Dep. at 19:9-22), and John Deere Health Care Inc. (now part United Healthcare) (*Id.* Ex. 13A, Sidwell Dep. 62:13-63:1.) TPPs with access to FDB data could readily observe the differences between WAC and AWP, both prices were published. (*Id.* Ex. 8A, Hartman Dep. 55:13-24; Proffer ¶ 22.)
- 15. Some TPPs carefully track drug trends and could observe the increasing drug costs allegedly caused by the increased AWP-WAC ratios. (*Id.* Ex. 13A, Sidwell Dep. 53:13-22; Proffer ¶ 23) (John Deere monitors claims processed on a daily basis, its costs per claim, many other drug trends); (*Id.* Ex. 21A, Cannon Dep. 11:2-17; Proffer ¶ 23) (SelectHealth tracks "national trends," "internal trends," and "contracting trends across the country.")
- 16. Each of the three largest PBMs published reports that highlighted the anomalous increase in AWPs in 2002. Medco's May 2003 Drug Trend Report reported that the 2002 AWP increases were "significantly higher than in years past." (See id., Ex. 15A, MEDCO 000195; Proffer ¶ 24.) Caremark's June 2003 TrendsRx Quarterly characterized the 2002 increases as "larger than normal," while the October 2003 edition reported that 2003 price increases were "close to 2001 levels and 2% below the AWP anomaly of 2002." (See id., Exs. 4D, 4E, CMK-AWP 0001793, 1797; Proffer ¶ 24.) Express Scripts Drug Trend Reports indicate that certain drugs showed unusual spikes in the cost of particular Appendix A drugs in 2002. For example, in 1999, 2000, and 2001, ESI reported percentage increases in Claritin 10 mg at 2.5%, 8.8% and 9.3%, respectively. Then in 2002, the cost of Claritin spiked to 21.1%, a significant increase compared with previous years. (Id. Ex. 6V, ESI-277-00012370-72; Proffer ¶ 24.)

- D. TPPs and PBMs Took Steps to Mitigate or Eliminate any Impact of FDB's Increased WAC-AWP Ratios.
- 17. One TPP, Promedica, received "rate relief" from ESI on all of ProMedica's reimbursed drugs, not just the drugs whose spreads had increased from 20% to 25%, in an amount *exceeding* the trend increases that were expected to result from FDB's spread changes. ESI achieved this mostly likely "by squeezing the pharmacies out of the margin they previously benefited from." (Schechter Sur. Decl. Ex. 29, PROMEDICA/NEC 00006-8.)
- 18. In around May 2002, another TPP, Harvard Pilgrim, reported that it was "in the process of renegotiating their retail contracts" because of FDB's spread changes, "potentially to a WAC+ agreement in lieu of AWP-%." (*Id.* Ex. 30, MDL-18.)
- 19. On April 16, 2002, the day after it received the ESI Urgent alert, wanting to "move quickly" in response to the alert, directed ESI as follows: "I'd like to put some quantity limits in place where we have none but should and, make some of our existing edits more stringent. We'll need to start with our fully funded plans and move to the self-funded afterwards." (Id. Ex. 25A, ESI-414-00004109-10.)
- 20. Another TPP, considered "specific step programs" to control brand drug dispensing and available "manufacturer programs" that could increase rebates if MDNY decided "to increase the differential between our co-payments." In turn, ESI adjusted rebate contracts with manufacturers to encourage greater manufacturer rebate payments in the 2003 contracts. (*Id.* Ex. 25B, ESI-414-00003758-59.)
- requested ESI to provide updates and analyses of specific trend due to FDB's spread change. (*Id.* Ex. 25D, ESI-414-00003722-28.)
- 22. TPP, requested "'drill-down' specifics per therapeutic category" so that it could "start strategizing management approaches." (*Id.* Ex, 24A, ESI-414-00001870-74.)

- 23. Indeed, ESI developed a model to analyze on an individual "client specific basis" how FDB's spread changes for the drugs in question would impact individual clients.

  requested that this model be used to analyze the extent of any impact on it. (*Id.* Ex. 25E, ESI-414-00003785-86.)
- 24. ESI has renegotiated pharmacy contracts to obtain steeper discounts before, during, and at the end of a contract term when available in the current market conditions. (Schechter Decl. Ex. 6A, Ignaczak Decl. ¶ 18; Proffer ¶ 18.) Additionally, plaintiffs' former expert, Susan Hayes, testified that if PBMs understood that retailer pharmacies were making more profits due to the alleged scheme, the "logical assumption" is that PBMs would negotiate to get better deals from retailers. (*Id.* Ex. 10A, Hayes Dep. 294:12-19; Proffer ¶ 18.)
- 25. In approximately the last quarter of 2002, employees in Caremark's pharmacy contracting department learned from Caremark's finance department that the spreads on a large number of brand name drugs increased from 20% to 25%. (*Id.* Ex. 4A Madsen Decl. ¶ 3; Proffer ¶ 18.) Caremark then took steps to mitigate the impact of this increase. (*See id.*)

### **APPENDIX B** DR. HARTMAN'S "FINDINGS" REGARDING TPP KNOWLEDGE AND RESPONSE

TOPIC	DR. HARTMAN'S FINDINGS	CONTRARY EVIDENCE <sup>1</sup>
The Effectiveness of (PBM) Express Scripts' Notification to TPP Clients of the Spread Increase	"[T]he evidence indicates that this PBM's information was incomplete, and that the PBM was ambiguous about whether and how to use the information to its benefit or to the benefit of its client TPPs."  (Hartman Rebuttal Decl. p. 2 (citing no evidence).)	App. A ¶¶ 1-10, 17, 20-25.  Proffer ¶¶ 8-18.
Other PBMs' and TPPs' Knowledge of the Spread Increase and Increased AWPs	"I find no evidence in discovery materials or in the public press that indicates or even suggests that other PBMs and TPPs knew of or acted upon knowledge of the 5% Scheme."  (Hartman Rebuttal Decl. p. 2 (citing no evidence).)	App. A ¶¶ 11-12, 16, 17-26.  Proffer ¶¶ 7, 18, 24.
	"There is no evidence of widespread knowledge of the 5% Scheme."  (Hartman Rebuttal Decl., Attach. C, p. 7 (citing no evidence).)	App. A ¶¶ 1-26.  Proffer ¶¶ 8-24.
	"I find no evidence in deposition testimony I have reviewed that demonstrates PBMs realized that the 5% Scheme had indeed occurred when	App. A ¶¶ 1-10, 17, 25, 26.  Proffer ¶¶ 7, 13, 17, 18.

<sup>&</sup>lt;sup>1</sup> Citations refer to the preceding Appendix A ("App. A") to McKesson Corporation's Surreply in Opposition to Class Certification and McKesson's Response to Plaintiffs' Proffer of Evidence and Counter-Proffer Regarding Evidence on Individual Issues ("Proffer").

TOPIC	DR. HARTMAN'S FINDINGS	CONTRARY EVIDENCE
	it occurred and that they aggressively competed away the reimbursement impact of the Scheme for their client TPPs."	
	(Hartman Rebuttal Decl., Attach. C, ¶ 14 (citing no evidence) (original emphasis).)	
	"In Attachment D, I provide references to additional deposition testimony materials that confirm that PBMs did not share information about	App. A ¶¶ 1-10.  Proffer ¶¶ 8-18.
	the Scheme with their clients."  (Hartman Rebuttal Decl., Attach. C, ¶ 16 (citing selected deposition testimony of 4 of 5 named plaintiffs and 4 other TPPs).)	
	"I find no evidence that more than a single PBM understood the 5% Scheme had been effectuated. Specifically, ESI came to realize the Scheme had been implemented some 8 months after the start of the Class Period. ESI acknowledged the increased AWP-to-WAC ratio in a draft letter dated April 5, 2002. The letter was being considered for client distribution; however, I have seen no evidence that the letter was widely distributed. Furthermore, the letter is fairly non-specific and uninformative"	App. A ¶¶ 1-1(), 26.  Proffer ¶¶ 8-18.
	(Hartman Rebuttal Decl., Attach. C, ¶ 17 (citing internal ESI email and uncirculated draft of ESI letter that was sent to TPP clients alerting them to Spread Increase) (original emphasis).)	

TOPIC	DR. HARTMAN'S FINDINGS	CONTRARY EVIDENCE <sup>1</sup>
	"I find no evidence in deposition testimony I have reviewed that demonstrates TPPs realized that the 5% Scheme had indeed occurred when it occurred and that they aggressively attempted to negotiate with their PBMs to counter the increased reimbursements induced by the Scheme."  (Hartman Rebuttal Decl., Attach. C, ¶ 18 (citing no evidence).)	App. A ¶¶ 9, 13, 17-24.  Proffer ¶ 16.
	"I have found no evidence of information reaching the market through the standard public sources of market information."  (Hartman Rebuttal Decl., Attach. C, ¶ 19 (citing no evidence).)	App. A ¶¶ 10, 16.  Proffer ¶¶ 7, 17, 24.
Changes in Discounts off AWP and Dispensing Fees	"The evidence shows no change in the two most important reimbursement terms in response to the 5% Scheme — the discount off AWP and the dispensing fee."  (Hartman Rebuttal Decl., Attach. C, p. 10 (citing no record evidence).)	App. A ¶¶ 17-2:6. Proffer ¶¶ 28-33.
Retroactive Renegotiations of Reimbursement Rates	"I conclude the following. The evidence of retroactive renegotiation of contracts is minimal at best. The examples put forward by Dr. Willig are both prior to the Scheme; there is no evidence that the one that might have helped negate the Scheme did indeed do so. Hence, such renegotiation has occurred, to a very limited degree, as a result of overall competitive market events; such	App. A ¶ 17. Proffer ¶ 26.

TOPIC	DR. HARTMAN'S FINDINGS	CONTRARY EVIDENCE <sup>1</sup>
	renegotiation will continue into the future for the same reasons. There is absolutely no evidence that such renegotiations have increased post-Scheme, as a result of the Scheme."  (Hartman Rebuttal Decl., Attach. C, ¶ 35 (citing no evidence).)	
Changes in Plan Design	"[C]hanges [in plan design and the level of copayments] were occurring prior to the Scheme. There is simply no evidence that these changes were accelerated in any way as a result of the Scheme, a Scheme about which so little information reached market participants."  (Hartman Rebuttal Decl., Attach. C, ¶ 36 (citing no evidence).)	App. A ¶¶ 20, 21, 23.  Proffer ¶¶ 39-42.